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| 26694 | 7590 | 12/05/2008 | EXAMINER | |
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| WASHINGTON, DC 20043-9998 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|------------------------------------|--|
| Office Action Summary | Application No. 10/538,686 | Applicant(s) HONG ET AL. | |
| | Examiner CHRISTOPHER R. STONE | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5 and 7-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed September 3, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1-13 are pending. Claims 2 and 6 are withdrawn as being directed to unelected species. Claims 1, 3-5 and 7-13 are currently under examination. Ceftazidime and an amino acid are the elected species of polar active substance and organic alkalizing agent currently under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Yata (EP 0091502 A1).

Claims 1, 3-5 and 8-12 are drawn to a composition comprising ceftazidime, an amino acid, a surfactant and a pharmaceutically acceptable excipient.

Yata teaches a pharmaceutical composition comprising ceftazidime (p. 7, compound XII), a basic amino acid (histidine, lysine or arginine, p. 10, lines 6-8), a

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surfactant (sorbitan fatty acid esters, HLB value = 7-15, carbon chain number 7-18, p. 8, lines 12 and 13, p. 9, lines 15 and 15) and preservatives (stabilizers and antiseptics, p. 11, lines 25 and 26) formulated into a capsule (p. 12, line 7). Yata et al further teaches that basic amino acids increase the absorbability of water-soluble compounds (p. 10, lines 17-19). Yata et al does not explicitly teach the partition coefficient of the polar active substance, the size of the ceftazidime-amino acid complex, of the properties of the substance in intestinal juices; however these properties are inherent to the composition (comprising the elected components) and are necessarily present. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Applicant argues that the amino acid serves a different purpose in the composition of Yata than in the instantly claimed composition and that there is no requirement for the amino acid to be an alkalizing agent, i.e. the amino acids can be neutral, basic or acidic (p. 6 of response filed, September 3, 2008). This is found unpersuasive because, as noted above, Yata explicitly teaches basic amino acids, including histidine, lysine or arginine. Additionally, the reason for the addition of the amino acid in the prior art does not need to be the same as Applicant's. Said reasoning does not structurally distinguish the instantly claimed composition from that of Yata.

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“[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In *re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Applicant further argues that a hydrophobic conjugate is not formed Yata as evidenced by examples where an amino acid is not used or an acid addition salt of an amino acid is used (p. 7 and 8 of the response filed, September 3, 2008). This is found unpersuasive because, as noted above, Yata teaches a composition comprising the instantly claimed and elected active substance, ceftazidime (p. 7, compound XII), the instantly claimed and elected organic alkalizing agent, a basic amino acid in free form (histidine, lysine or arginine, p. 10, lines 6-10), and the instantly claimed surfactant (sorbitan fatty acid esters, HLB value = 7-15, carbon chain number 7-18, p. 8, lines 12 and 13, p. 9, lines 15 and 15). Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In *re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) It is noted that In *re Best* (195 USPQ 430) and In *re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the

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applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yata (EP 0091502 A1).

Yata discloses the aforementioned composition, but does not explicitly teach the charge ratio of the ceftazidime and amino acid. However, Yata teaches that the ceftazidime can be present in the composition at 2.5-50% by weight (p. 8, lines 11-14) and that the amino acid (e.g. histidine) can be present in the composition at 0.5-20% by

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weight, i.e. the ceftazidime and amino acid may be present in the composition at a 1:1 weight ratio. A 1:1 weight ratio (histidine:ceftazidime) confers a 4.1:1 molar ratio (MW histidine = 155.16, MW ceftazidime = 636.6) and therefore a 4.1:1 charge ratio, since the ceftazidime has one anion and histidine has one cation. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the instantly claimed invention to prepare the composition of Yata using a 1:1 weight ratio of histidine:ceftazidime, since this range was taught to be effective in preparing said composition, thus resulting in the instantly claimed composition (with the instantly claimed charge ratio) with a reasonable expectation of success.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yata (EP 0091502 A1) in view of Bachynsky et al (US Patent 5190748).

Yata et al teaches the aforementioned method, but does not teach the composition comprising an enteric coating. Bachynsky et al teaches the oral administration of ceftazimide (column 2, lines 37-61, column 4, lines 63 and 64). Bachynsky et al further teaches that enteric coating of ceftazimide protects the compound from gastric fluid upon oral administration (column 8, lines 27-34). Therefore it would have been obvious to add an enteric coating to the composition of Yata to protect the ceftazimide from degradation in the gastric juices, thus resulting in the practice of the instantly claimed composition with a reasonable expectation of success.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

03December2008

CRS

/Patricia A. Duffy/

Primary Examiner, Art Unit 1645